JAN 2 4 2006

K053235
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510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	MedicSense, Ltd. Galdani Bldg 58b Amal St. Kiriat Arie, Petach Tikya, Israel 47103 www.medicsense.com
1. (b)	***Manufacturer Address:***	NSK Nakanishi, Inc. 700 Shimohinata, Kanuma-shi Tochigi-ken, Japan 322-8666
	Mfg. Phone:	1-289-64-3422
	Contact Person:	Masato Hamada, North America Manager
	Date:	November 13, 2005
2.	***Device & Classification Name:***	Locator, Root, Apex, Class 2, Product Code LQY, unclassified NSK Precision Apex Locator (PAL)
3.	***Predicate Device:***	MedicNRG Electronic Apex Locator (K032743)
4.	***Description:***	The NSK Precision Apex Locator is a dental medical device which has the ability to measure the depth of the root canal by electronic means.
5.	***Intended Use:***	The NSK Precision Apex Locator is intended for the measurement of the length of the root canal for purposes of performing root canals and related dental procedures, for use by a trained professional in general dentistry.
6.	***Comparison of Technological Characteristics:***	With respect to technology and intended use, the NSK Precision Apex Locator is substantially equivalent to its predicate device which is the MedicNRG Electronic Apex Locator. The primary difference is that the NSK device utilizes a LCD display whereas the NRG device utilizes a LED display. Based upon testing results, NSK believes this difference does not raise additional safety of efficacy concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2006

Mr. George Hattub
Senior Staff Consultant
MedicSense, U.S.A.
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K053235
Trade/Device Name: NSK Precision Apex Locator
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: LQY
Dated: November 15, 2005
Received: November 23, 2005

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053235

Device Name: NSK Precision Apex Locator

Indications For Use: The NSK Precision Apex Locator is intended for the measurement of the length of the root canal for the purpose of performing root canals and related dental procedures, for use by a trained professional in general dentistry.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Beck DDS for Dr. Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, General Hospital
Dental Devices

510(k) Number K053235